

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 6-15 and 20-30 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for the claim amendments is found in the molecular weight cut-off of 50 kDa at page 6, line 14, of the specification and Example 2 describing separation of RNA from other low molecular weight soluble cell material at page 11, lines 19-20, of the specification.

35 U.S.C. 103 – Nonobviousness

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* (“Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). The use of hindsight reasoning is impermissible. See *id.* at 1397 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning”). Thus, a prima facie case of obviousness requires “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” *Kahn* at 1335; see *KSR* at 1396. An inquiry is required as to “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1396. But a claim directed to a combination of prior art elements “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* Finally, a determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 6, 8-13 and 20-30 were rejected as allegedly unpatentable over Tanekawa et al. (U.S. Patent 4,303,680) in view of Keller et al. (U.S. Patent 4,623,723), with evidence provided by Kanegae et al. (U.S. Patent 4,810,509) and Chae et al. (Biore-source Technol. 76:253-258, 2001). Applicants traverse.

The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time this invention was made to improve the process for producing a flavoring composition containing 5'-ribonucleotides disclosed by Tanekawa with Keller's method of separating the RNA present in the released cell contents from other soluble cell material. Applicants respectfully disagree.

Applicants' claims require separation of RNA (i.e., a high molecular weight material) from low molecular weight soluble cell materials like inorganic compounds, vitamins, carbohydrates (e.g., trehalose), free amino acids, peptides, and small proteins. See Example 2, especially page 11, lines 9-12, of the present specification. To clarify this difference in molecular weights, the present claims are amended to specify that the other soluble cell material is smaller than 50 kDa.

In contrast, Keller uses filtration to separate RNA from DNA (i.e., both high molecular weight materials), instead of separating RNA from other soluble cell materials that are smaller than 50 kDa (i.e., low molecular weight materials) as required by Applicants' claims. One of ordinary skill in the art would know that DNA is much larger than 50 kDa, and hence that the low molecular weight material as defined in the present specification cannot possibly be DNA. Cf. Applicants' claim 30 that requires ultrafiltration with a molecular weight cut-off from 10 kDa to 50 kDa.

In accordance with Applicants' claimed invention, it is highly likely that RNA and DNA would both be retained in the same fraction if filtration was used for separation (i.e., the retentate in Applicants' claims 12 and 30). Therefore, one of ordinary skill in the art seeking to modify Tanekawa's process so that RNA is separated from low molecular weight soluble cell material would not have consulted Keller because the latter teaches the separation of RNA from DNA.

Finally, no reasonable expectation of success was provided by the Examiner to combine Tanekawa and Keller to separate RNA from low molecular weight soluble cell materials that are smaller than 50 kDa.

Thus, the combination of Tanekawa and Keller does not render obvious Applicants' invention as represented by independent claims 6, 20 and 30. Moreover, claims 8-13 and 21-29 depending from independent claim 6 are also not rendered obvious by the cited documents because all limitations of an independent claim are incorporated in its dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, this obviousness rejection should be withdrawn.

Claims 6-7 and 25 were rejected as allegedly unpatentable over Tanekawa et al. (U.S. Patent 4,303,680) in view of Keller et al. (U.S. Patent 4,623,723), and further in view of Potman et al. (U.S. Patent 5,288,509). Applicants traverse.

For the reasons explained above regarding the Examiner's allegation that independent claim 6 is rendered obvious by Tanekawa in view of Keller, the two documents' failure to disclose the claimed invention is not remedied by the attempt to combine their disclosures with Potman. The latter document was cited for an earlier processing step of treating cells with a protease, which is before the initial separation of RNA from DNA, to deactivate the native enzymes prior to the cell's enzymatic degradation, instead of the later step of separating RNA from soluble cell materials smaller than 50 kDa as required by Applicants' claims.

Among those failures is the lack of a reasonable expectation of success that the prior art process would separate RNA from low molecular weight soluble cell material. Applicants submit that this feature of their claimed invention is sufficient to distinguish over the cited documents so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Claims 6 and 14-15 were rejected as allegedly unpatentable over Tanekawa et al. (U.S. Patent 4,303,680) in view of Keller et al. (U.S. Patent 4,623,723), and further in view of Tsuda et al. (U.S. Patent 4,374,981). Applicants traverse.

For the reasons explained above regarding the Examiner's allegation that independent claim 6 is rendered obvious by Tanekawa in view of Keller, the two documents'

failure to disclose the claimed invention is not remedied by the attempt to combine their disclosures with Tsuda. The latter document was cited for a later processing step of separation, which is after the initial separation of RNA from DNA, to further purify the 5'-ribonucleotides by the removal of compounds having a higher molecular weight than 5'-ribonucleotides, instead of the earlier step of separating RNA from soluble cell materials smaller than 50 kDa as required by Applicants' claims.

Among those failures is the lack of a reasonable expectation of success that the prior art process would separate RNA from low molecular weight soluble cell material. Applicants submit that this feature of their claimed invention is sufficient to distinguish over the cited documents so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 103 rejections is requested because the claims would not have been obvious to one of ordinary skill in the art when this invention was made.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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